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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,719	03/09/2004	Mark G. Currie	14184-043001	1787

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FISH & RICHARDSON PC  
P.O. BOX 1022  
MINNEAPOLIS, MN 55440-1022

EXAMINER
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TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/796,719

Applicant(s)

CURRIE ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 21-79 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1,5 and 8-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/05, 11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to the election, received 10/26/06, in which applicant elected group I, claims 1-20, 25, 35-38. Applicant further elected SEQ ID NO:31, which reads on claims 1, 5, 8-13 and 20.

Claims 2-4, 6-7, 38, 46-54, 71-73 and 77-79 are cancelled.

Claims 14-19, 21- 37, 39-45, 55-70, and 74-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected peptides, there being no allowable generic or linking claim.

Applicant's election with traverse of group II is acknowledged. The traversal is on the ground(s) that the pharmaceutical compositions of group II also comprise a peptide within group I. This is not found persuasive because the pharmaceutical compositions are drawn to a different chemical structure than the peptide, requiring a search which is not co-extensive with the peptide search..

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 5, 8-13 and 20 are pending.

### ***Information Disclosure Statement***

The information disclosure statements received 1/31/05 and 11/3/05, are acknowledged. A signed copy is enclosed hereto.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, and 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “A purified polypeptide comprising the amino acid sequence (I): Xaa1, Xaa2, Xaa3, Xaa4, Xaa5, Cys6, Cys7, Xaa8, Xaa9, Cys10, Cys11, Xaa12, Xaa13, Xaa14, Cys15, Xaa16, Xaa17, Cys18, Xaa19, Xaa20, Xaa21 (SEQ ID NO; 119) wherein: Xaa1, Xaa2, Xaa3, Xaa4, Xaa5 is missing and Xaa9 is Phe, Trp, or Tyr.” This is indefinite since it is unclear what amino acid substitutions, if any, can be made for the undefined variables, i.e., Xaa8, Xaa12, Xaa13, Xaa14, Xaa16, Xaa17, Xaa19.

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 USC 112, second paragraph.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 5, and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Giannella (J. of Lab. and Clin. Med., 1995, vol. 125, no. 2, pp-173-181).

The instant invention is drawn to a purified polypeptide comprising the amino acid sequence (I): Xaa1, Xaa2, Xaa3, Xaa4, Xaa5, Cys6, Cys7, Xaa8, Xaa9, Cys10, Cys11, Xaa12, Xaa13, Xaa14, Cys15, Xaa16, Xaa17, Cys18, Xaa19, Xaa20, Xaa21 (SEQ ID NO; 119) wherein: Xaa1, Xaa2, Xaa3, Xaa4, Xaa5 is missing and Xaa9 is Phe, Trp, or Tyr.

Giannella discloses E. coli heat stable enterotoxins, guanylins and their receptors. The structure of E. coli STh, a purified 19 amino acid peptide (N-S-S-N-Y-C-C-E-L-C-C-N-P-A-C-T-G-C-Y) is shown in figure 1, page 174. The claims are silent on the amino acids required for Xaa19, Xaa20 and Xaa21, so the examiner is assuming Xaa19- Xaa21 are not present, when comparing the prior art to the instant claims.

Therefore, the reference is deemed to anticipate the instant claims above.

### ***Conclusion***

Claims 1, 5, 8-13 are rejected. Claim 20 is drawn to allowable subject matter

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT

1654

12/7/06

RT

  
ANISH GUPTA  
PRIMARY EXAMINER